

REMARKS

Kindly enter the above amendments prior to calculation of the filing fee. Claim 1 has been cancelled by this amendment. Claims 2 and 3 have been added. It is respectfully submitted that the presently pending claims obviate all of the rejections cited by the Examiner in the parent application. However, it is requested that the following remarks be considered.

Terano et al., U.S. Patent No. 5656434, teaches the use of a serum which was freeze-dried as the assay control serum (col. 8, lines 57-59) in the ELISA (col. 7, line 8). The analyte to be measured is a cardiac glycoside, such as ouabain or digoxin (col. 6, line 65-col. 7, line 3).

Terano et al. does not, however, teach the use of a dry analytical element to measure uric acid, alkaline phosphatase, urea nitrogen, or creatinine. Further, Terano et al. does not recognize the problem of inconsistencies between wet analysis and dry analysis in the measurement of particular blood components such as uric acid, alkaline phosphatase, urea-nitrogen, creatinine, etc. Although Terano et al. refers to alkaline phosphatase, it is used as a label in the ELISA (col. 6, line 21) rather than having its level measured in the assay. In summary, Terano et al. does not recognize the problem or teach the solution that is described and claimed in the present application.

Stone, U.S. Patent No. 4136159, teaches the use of a control serum comprising a vial of lyophilized human serum (col. 6, lines 54-55) in an assay radio of folates (title of invention).

Stone does not teach the use of a dry analytical element to measure uric acid, alkaline phosphatase, urea-nitrogen, creatinine, etc. and does not recognize or identify the problem of inconsistencies between wet analysis and dry analysis in the measurement of particular components, such as uric acid, alkaline phosphatase, urea-nitrogen or creatinine.

Sugiyama et al., U.S. Patent No. 5948895, teaches the use of a mixture containing serum is lyophilized (Abstract) which is used as a maker for clinical examination (col. 1, lines 14-15).

However, Sugiyama et al. does not teach the use of a dry analytical element to measure uric acid, alkaline phosphatase, urea nitrogen, creatinine, etc. and does not recognize or identify the problem of inconsistencies between wet analysis and dry analysis in the measurement of particular components, such as uric acid, alkaline phosphatase, urea-nitrogen or creatinine.

Pinto et al., U.S. Patent No. 3993585, also does not teach the use of a dry analytical element to measure uric acid, alkaline phosphatase, urea nitrogen, or creatinine and does not recognize or identify the problem of inconsistencies between wet analysis and dry analysis in the measurement of particular components, such as uric acid, alkaline phosphatase, urea-nitrogen, creatinine, etc. Moreover, the control serum used Pinto et al. is dialyzed (col. 2, lines 41-41).

It is respectfully submitted that the present application is in form for allowance. It is also submitted that all of the objections and rejections made by the Examiner in the Office Action dated June 11, 2003, in the parent application have been overcome by the amendments made herein. It is to be noted that the priority document is forthcoming under separate cover. The Examiner is invited to contact the Applicants' attorney at the phone number indicated below should there be any questions.

Respectfully submitted,

By _____
Jules E. Goldberg
Reg. No. 24,408
REED SMITH LLP
599 Lexington Avenue
New York, NY 10022
(212) 521-5403
Attorney for Applicant



Dated: September 11, 2003

APPENDIX A

A control serum for a dry process is provided that ~~does~~ does not show misfit in measurement values by the dry process and a wet process. The above-mentioned control serum is obtained by freezing or freeze-drying a control serum without dialysis.